K010846
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Sterling Medivations, Inc.
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Wayzata, Minnesota 55391
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510(k) SUMMARY

Date Submitted: March 20, 2001

Submitter: Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391
Company Phone 952-473-7971, Company Fax 952-473-4758

Contact: Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 408-297-9474 ext. 0 voice mail 21 or 650-949-0470
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Trade Name of Device: Simplicity™ Silver Soft Infusion Set for infusion and/or injection of fluids into the body below the surface of the skin when attached to an external pump or syringe.

Common Name of Device: Intravascular administration set.
Classification Name: Percutaneous intravascular catheter.

Predicate Device: Maersk Medical Contour™ Infusion Set, K991759 that is currently supplied to and sold by MiniMed® as the MiniMed Silhouette® Infusion Set, Maersk Medical Pureline™ Comfort™ Infusion Set, K972135, the MiniMed Polyfin with Wings Infusion Set, K964455 that is currently supplied to and sold by MiniMed® and the Disetronic Rapid Subcutaneous Infusion Set, K003977 that is currently supplied to and sold by Disetronic Medical Systems AG.

Description of the New Device: Sterling Medivations Inc.'s ("SMI") Simplicity Silver Soft Infusion Set is designed for infusion and/or injection of fluids into the body below the surface of the skin when attached to an external pump or syringe.

The Simplicity Silver Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing MiniMed Silhouette Infusion Set, Maersk Medical Pureline™ Comfort™ Infusion Set, K972135, the MiniMed Polyfin with Wings Infusion Set, K964455 that is currently supplied to and sold by MiniMed® and the Disetronic Rapid Subcutaneous Infusion Set, K003977 that is currently supplied to and sold by Disetronic Medical Systems AG and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from FEP, (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a threaded reservoir connector.

The Simplicity Silver Soft Infusion Set is an infusion administration set, connecting to a medicine reservoir or syringe that is placed in an external infusion device and inserted in the subcutaneous tissue of a patient. The SMI Simplicity Silver Soft Infusion Set may be used with any infusion device that delivers continuous or intermittent flow.

The administration set attaches to the reservoir/syringe by means of a threaded connector, and subcutaneously in the patient through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP). The connecting tubing is made from a polyethylene tube.

The 25 gauge-indwelling catheter is introduced into the subcutaneous tissue by a removable 27-gauge introducer needle formed from AISI 304 stainless steel. The introducer needle is removed and a connector needle is attached to the hub fixed to the indwelling catheter. This seal on the connector needle mates with the indwelling catheter

hub that forms a seal that permits the infusion of medication without leakage. The connector needle is made from AISI 304 stainless steel and it is connected to the connecting tubing. The connector tubing proximal end is attached to a threaded connector for attachment to the medicine reservoir.

Intended Use of the New Device: The intended use of the Simplicity Silver Soft Infusion Set is to provide a means to for infusion and/or injection of fluids into the body below the surface of the skin when attached to an external pump or syringe.

Comparison of the Technological Features of the New Device and Predicate Device:

The Simplicity Silver Soft Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Maersk Medical Contour™ Infusion Set, K991759 sold by MiniMed as the Silhouette Infusion Set, Maersk Medical Pureline™ Comfort™ Infusion Set, K972135, and the Disetronic Rapid Subcutaneous Infusion Set, K003977 that is currently supplied to and sold by Disetronic Medical Systems AG and it has the same intended use.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the MiniMed Silhouette Infusion Set.

The differences that exist between the new and predicate device are as follows:

1. The new device has a connecting tube of Polyethylene and the predicate device has a connecting tube of co-extruded connecting tube Polyethylene id and PVC OD.

2. The new device has a separate septum in the connecting hub to allow for the injection of insulin by a insulin pen or syringe and the predicate device has a septum for the same purpose in the infusion hub.

Performance Data Supporting Substantial Equivalence: To prove substantial equivalence the Simplicity Silver Soft Infusion Set meets the catheter requirements of:

- CDRH 21 C.F.R. Section 880.5440 Intravascular administration set
- ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements)
- ISO 10555 Sterile, single use intravascular catheters (Part 5: Peripheral Catheters).
- ISO 11135:1994 Medical devices -- Validation and routine control of ethylene oxide sterilization
- ISO 11138-2:1994 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization.
- ISO 9626: 1991 Stainless Steel needle tubing for the manufacture of medical devices.
- ISO 11607: 1997 Packaging for terminally sterilized medical devices.
- ISO 8535: 1991 Sterile single use syringes, with or without needle, for insulin.
- FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end product endotoxin test for human and animal parenteral drugs, biological products, and medical devices.
- ODE Blue Book Memorandum #K90-1.
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing.

And the design process adhered to is the Center for Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed,

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2001

Mr. Joel Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
180 Ferndale Road South
Wayzata, Minnesota 55391

Re: K010846
Trade Name: Simplicity Silver Set Soft Infusion
Regulatory Class: II
Product Code: FPA
Dated: March 20, 2001
Received: March 21, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Simplicity Silver Soft Infusion Set

Indications For Use:

The intended use of the Simplicity Silver Soft Infusion Set is to provide a means to for infusion and/or injection of fluids into the body below the surface of the skin when attached to an external pump or syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010546